

July 12, 2004

Color Pigments Manufacturers Association, Inc  
Attn: J. Lawrence Robinson, President  
Suite 102  
300 North Washington Street  
Alexandria, Virginia 22314

Dear Mr. Robinson:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-oxetanone, 4-methylene (Diketene) posted on the ChemRTK HPV Challenge Program Web site on February 25, 2004. I commend the Color Pigments Manufacturers Association, Inc, Diketene Derivatives Task Force for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. General. EPA was not able to locate any information on the ICCA or OECD HPV websites regarding country sponsorship or status in these programs. Since the submitter is relying on these programs to address any data gaps, EPA needs to know whether these will be finished within the time frame for the HPV Challenge Program.
2. Health Effects. In the test plan the submitter states that the repeated-dose, genetic and reproductive/developmental toxicity endpoints will be addressed with data from two analogs, ethyl acetoacetate and methyl acetoacetate. However, the rationale presented in the test plan is too general to adequately support the submitters' justification for using the analog data. There needs to be more than a "strong assumption" supporting the use of the analogs. Perhaps the assessment required under the OECD SIDS Program will more fully address this issue. In addition, if the use of the analogs is warranted robust summaries for the specific endpoints addressed using the analog data need to be provided in the data set for Diketene. It is not sufficient to merely refer to other documents in EPA's possession.
3. Ecological Effects. EPA agrees that any toxicity associated with Diketene will be from acetoacetic acid (AAA) due to the very rapid hydrolysis of Diketene to AAA. The submitter has used ECOSAR predictions for AAA to address the ecological endpoints, but alludes to the possibility that data may have or will be generated under the ICCA/OECD SIDS Programs. This further reinforces the need for a coordinated approach to addressing the SIDS-related endpoints.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that the Task Force advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: W. Penberthy  
M. E. Weber